Indiana State Department of Health
Indianapolis, IN

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TO: All Local Health Departments
Attention: Chief Food Specialist

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SUBJECT: Guidance for proper implementation of Sections 109 and 136 of Indiana State Department of Health, Retail Food Establishment Sanitation Requirements Rule 410 Indiana Administrative Code (IAC) 7-20

Introduction:

The recent news relating to the series of viral outbreaks on cruise ships, nursing homes and schools prompts a revisit to the above sections of the retail food code. The many cases of Norwalk-like viral outbreaks can almost always be attributed to the basic lack of controls as it relates to hand washing and restriction of the person who is ill. The Food and Drug Administration (FDA) has publicly stated it is vital that the human hands be removed from the handling of ready-to-eat foods whenever it is possible.

Sections of 410 IAC 7-20 to be discussed:

Section 136 "Preventing Contamination from Hands" states the following:

(a) Food employees shall wash their hands as specified under section 106 of this rule.
(b) Food employees shall not contact exposed, ready-to-eat food with hands that have not been washed as specified in sections 107 and 108 of this rule, and shall use suitable utensils, such as:
    (1) deli tissue;
    (2) spatulas;
    (3) tongs;
    (4) single use gloves; or
    (5) dispensing equipment;
    when utensils can be used.
(c) Food employees shall minimize bare hand and arm contact with exposed food that is not in a ready-to-eat form.[S]

Section 109 Hand Sanitizers, states the following:

(a) A hand sanitizer and a chemical hand sanitizing solution used as a hand dip shall:
  (1) have active antimicrobial ingredients that are safe and effective for application to human skin;
  (2) have components that are:
    (A) regulated for the intended use as food additives as specified in 21 CFR 178;
    (B) generally recognized as safe (GRAS) for the intended use in contact with food within the meaning of section 201(s) of the federal Food, Drug, and Cosmetic Act; or
    (C) exempted from the requirement of being listed in the federal food additive regulations as specified in 21 CFR 170.39; and be applied only to hands that are cleaned as specified under section 106 of this rule.

(b) If a hand sanitizer or a chemical hand sanitizing solution used as a hand dip does not meet the criteria specified under subsection (a)(2), use shall be:
  (1) followed by thorough hand rinsing in clean water before hand contact with food or by the use of gloves; or
  (2) limited to situations that involve no direct contact with food by the bare hands.

(c) A chemical hand sanitizing solution used as a hand dip shall be maintained clean and at a strength equivalent to at least one hundred (100) ppm chlorine.

Sections 89, 149, and 265 are also mentioned as supportive sections in the discussion.

Discussion:

In November, 1999, the National Advisory Committee for Microbiological Criteria for Foods (NACMCF), concluded that bare hand contact with ready-to-eat foods can contribute to the transmission of foodborne illness. They further agreed that the transmission could be interrupted. The NACMCF recommended exclusion/restriction of ill foodhandlers as the first strategy and recognized that this intervention has limitations, such as trying to identify and manage asymptomatic food workers. When the FDA reviewed and analyzed epidemiological data on foodborne illness outbreaks caused by fecal-oral pathogens, 93% of the foodborne illnesses were caused by ill food workers preparing food. This finding illustrates the problem caused by ill food workers who continue to prepare food.

Depending on the microbial contamination level on the hands, handwashing with plain soap and water may not be an adequate intervention to prevent the transmission of pathogenic microbes from bare hand contact of ready-to-eat foods. Food workers infected with fecal-oral pathogens can shed viral and protozoan pathogens in the feces at levels of up to 10^8 viral particles or oocysts per gram of feces. Having a high potential contamination level on the hands combined with a very low infectious dose necessary to

cause infection are the reasons FDA believes that handwashing alone is not an effective single barrier in the transmission of these fecal-oral pathogens. The infective dose for Hepatitis A is as low as 10 virus particles and Norwalk-like virus is also believed to be very low.

The Centers for Disease Control (CDC) now estimates that Norwalk-like viruses are the leading cause of foodborne illness in the United States. The CDC also reported that hands are the most important means by which enteric viruses are transmitted. Research has shown the viral transfer rate from contaminated hands to ready-to-eat food to be about 10% and that proper handwashing will significantly reduce the chance of transmitting pathogenic viruses. However, with heavy initial contamination of the hands, especially in the subungal space between the fingers, a basic 2-3 log reduction handwash procedure may not be adequate to prevent the transmission of viral foodborne illness.

The three interdependent critical factors in reducing foodborne illness transmitted through the fecal-oral route, identified by the NACMCF, include:

1.) Exclusion/restriction of ill food workers;

2.) Proper handwashing; and

3.) No bare hand contact with ready-to-eat foods.

Each of these factors are inadequate when utilized independently and may not be effective, however, when all three factors are combined and utilized properly, the transmission of fecal-oral pathogens can be controlled.

Pathogens can also be transferred to food from utensils that have not been properly cleaned, sanitized or stored. They may also be passed on by consumers or employees directly, or indirectly from used tableware or food containers. Some pathogenic microorganisms survive outside the body for considerable periods of time. Food that comes in contact directly or indirectly with surfaces that are not cleaned and sanitized is susceptible to such contamination.

Section 89 defines "utensil" as a food contact implement used in contact with food. A food utensil should be designed and used to prevent cross-contamination and/or bare hand contact with ready-to-eat food. Therefore gloves, when used as a utensil, must meet the applicable requirements relating to design and usage of food contact surfaces of equipment. On-site evaluations can be made by the regulatory authority to determine if a utensil is improperly designed for the task, or whether a food employee is misusing a food contact utensil, such as gloves.

Once a food employee begins to use a utensil, such as a ladle, spatula, or knife that has been previously cleaned and sanitized, then it is considered an in-use utensil. In-use utensils, when used on a continuous basis during preparation or dispensing, must be cleaned and sanitized on a schedule that precludes the growth of pathogens that may have

been introduced onto utensil surfaces. In-use utensils must also be stored in a manner that prevents contamination as specified in Section 265. Furthermore, single use utensils, such as disposable gloves, must be properly used and be disposed of when they become contaminated as required in section 149. Hands must then be properly washed before a new pair of gloves is to be worn.

For these public health reasons, Section 136 prohibits food employees from bare-hand contact of ready-to-eat foods **when utensils can be used**. There are a very limited numbers of examples where a utensil has been demonstrated to not work and therefore, it is possible that you may experience one of these situations. Sandwich preparation and other similar operations would not be included as an exempted process. A utensil use is the rule rather than the exception.

In addition, it is necessary to discuss the use of hand sanitizers by food handlers. Since the May 25, 2001 guidance document was provided, new developments in the hand sanitizer approval process have evolved. The following hand sanitizer products have components that are Generally Recognized As Safe (GRAS) for the intended use in contact with food, so therefore are exempted from the requirements of being listed in the federal food additive regulations and/or being regulated for the intended use as a food additive. These products can be used on washed hands without the need to rinse the product off or to use gloves as discussed above. The products and manufacturers are:

GOJO® manufactures: Purell® Hand Sanitizer

Kay Chemical Company®, subsidiary of ECOLAB® manufactures:

ACTIGEL™ Hand Sanitzer
EcoCare™ 550S Hand Sanitizer
Digisan™ Hand Sanitizer
Sanigizer® Plus Hand Sanitizer
McD® Hand Sanitizer
Puritan® Hand Sanitizer
ALPHASAN™ Hand Sanitizer

Studies have shown that these products are effective on bacterial pathogens, such as Salmonella and E. coli 0157:H7. However, documentation has not been presented to FDA regarding the effectiveness of hand sanitizers against viral or protozoan pathogens. Therefore, if a person decides to use one of the above hand sanitizers then they must continue to avoid the handling of ready-to-eat food products with their bare hands. Utensils must continue to be used even if these products are utilized.

Conclusion:

In conclusion, the epidemiological data demonstrates that to control diseases of concern in the food industry it is necessary that three (3) barriers be in place:

1.) Strict restriction and/or exclusion of infected food employees policies must exist;

2.) Bare hand contact of ready-to-eat foods must be eliminated or severely minimized; and
3.) Proper hand washing must occur at all times.

In addition, only those hand sanitizer products listed may be used in conjunction with proper hand washing without the need to remove the product from the hands. If food employees will properly follow these requirements, diseases spread by the fecal-oral route will be controlled.

If you have any questions or would like to further discuss, feel free to contact your area field representative or this office at 317/233-7360.